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LAW OFFICE OF COLLEN A. BEARD, LLC
P. O. BOX 1064
DECATUR, GA 30031-1064

EXAMINER	
GHALI, ISIS A D	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TROY HOLLAND, HASSAN CHAOUK,
BRUKTAWIT ASFAW, STEPHEN GOODRICH,
ADRIAN HUNTER and VIMALA FRANCIS[1]

Appeal 2008-4671
Application 09/960,449
Technology Center 1600

Decided: December 9, 2008

Before JAMES T. MOORE, *Vice Chief Administrative Patent Judge*, and RICHARD E. SCHAFER and SALLY G. LANE, *Administrative Patent Judges*.

MOORE, *Vice Chief Administrative Patent Judge*.

DECISION ON APPEAL

1

2 STATEMENT OF THE CASE

3 The Appellants appeal under 35 U.S.C. § 134 (2002) from a final

4 rejection of claims 1-4, 8-11, 13-17, 21-23, 25, and 27-29.[2] We have

5 jurisdiction under 35 U.S.C. § 6(b) (2002).

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[1] The real party in interest is BioCure, Inc. (App. Br. 1).
[2] Claims 5-7, 12, 18-20, 24, and 26 have been canceled. (See App. Br. 9-11).

The Appellants' claims are directed to compositions and methods of forming a spray wound dressing, which forms in place on the wound.

Claim 1 reads as follows:

> 1. A hydrogel wound dressing formed by spray delivery of a liquid composition to the wound, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form a hydrogel *in situ* on the wound, wherein the pendant crosslinkable groups are acrylamide groups containing olefinically unsaturated groups, and wherein the composition includes a crosslinking initiator that is not bound to a macromer or another polymer.

(App. Br. App. 9).

THE EVIDENCE

The Examiner relies upon the following as evidence in support of the rejections:

Chudzik	US 6,007,833	Dec. 28, 1999
Sawhney	US 6,179,862 B1	Jan. 30, 2001

THE REJECTIONS

The following rejections are before us for review:

1. Claims 1-4, 8-11, 13-17, 21-23, 25 and 27-29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

2. Claims 1, 2, 8, 9 and 29 stand rejected under 35 U.S.C. § 103(a) over Chudzik.

3. Claims 3, 4, 10, 11, 13-17, 21-23, 25, 27 and 28 stand rejected under 35 U.S.C. § 103(a) over the combination of Chudzik and Sawhney.

We AFFIRM.

ISSUES

Have the Appellants established that the Examiner erred in determining that the claim phrases "initiator that is not bound" and "another polymer" is not adequately described in the original written description of the claimed invention?

Have the Appellants established that the Examiner erred in determining that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the known macromers and initiators for their known functions to use as a spray dressing for a wound?

FINDINGS OF FACT

The record supports the following findings of fact by a preponderance of the evidence.

1. The Appellants' claim 1 recites that the spray would dressing "includes a crosslinking initiator that is not bound to a macromer or another polymer." (Br. Appx. At 1).

2. The Appellants' specification does not contain a statement that the cross-linking initiator of the invention composition is "not bound to a macromer or another polymer." (See App. Br. 4).

3. The specification does refer to the term "initiator" in a limited number of instances - to describe photoinitiators, a redox initiator and a borate initiator. (See App. Br. 3)(citing Specification p. 9, ll. 22-25; p. 17, l. 13; p. 19, l. 1; p. 20, l. 2).

4. The specification does not describe that the photoinitiators, redox initiator, or borate initiator is "not bound to a macromer or another

polymer." (See Specification p. 9, ll. 22-25; p. 17, l. 13; p. 19, l. 1; p. 20, l. 2).

5. Chudzik describes a crosslinkable macromer system that comprises two or more polymer-pendent polymerizable groups and one or more polymer-pendent initiator groups. (Chudzik Abstract).

6. Chudzik describes that the matrices formed by the invention are useful in tissue adherence (wound dressing). (Id. 1:10-15).

7. Specifically, Chudzik describes a macromer system in liquid form and is applied to the wound site where it is subsequently formed into a flexible polymeric matrix, i.e., a hydrogel wound dressing, upon exposure to light. (Id. 10:3-6).

8. Chudzik describes that a wide range of drugs and bioactive materials can be delivered using the invention, including, but not limited to, growth factors, anti-inflammatory agents, antithrombogenic agents, and anitmicrobial agents. (Id. 9:38-44, 10:11-14).

9. Chudzik describes that the biostable matrix-forming backbones of the invention are water soluble and include, e.g., polyvinyl alcohol (PVA). (Id. 5:24-30).

10. Chudzik describes that preferred polymerizable groups include acrylamides. (Id. 5:51-53).

11. Chudzik also describes that the acrylamide groups contain olefinically unsaturated groups. (Final Rejection, Jun. 13, 2007, p. 5).

12. Chudzik also describes preparing and evaluating two polymer solutions, one containing a polymer-bound initiator and one containing non-polymer-bound initiator. (Chudzik14:45-15:32).

13. According to Chudzik, the polymer solution containing the bound initiator "formed matrices more rapidly and more completely" than the polymer solution containing the unbound initiator. (15:28-31).

14. In other words, with regard to matrix formation, Chudzik describes that a polymer solution containing unbound initiator is functional, albeit inferior, to a solution with bound initiator. (FF-9, 10).

15. Chudzik primarily differs from the claimed invention in that it does not describe that the liquid composition is formed by spray delivery.

16. Sawhney describes methods of forming hydrogels *in situ* by using a sprayer to apply crosslinkable components to tissue surface. (Sawhney 1:1-10, 2:1-8).

17. Sawhney describes that the spray delivery system causes the crosslinkable solutions to become atomized and mixed in a gas flow to form a spray. (Id. 2:9-18).

18. Sawhney also describes that spray delivery is suitable for liquid compositions comprising water soluble crosslinkable macromers. (Id. 5:32-36).

19. Nitric oxide is a known antithrombotic. (Ans. 12).

PRINCIPLES OF LAW

A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley,* 27 F.3d 551, 553 (Fed. Cir. 1994).

ANALYSIS

I. The Written Description Rejection.

Claims 1-4, 8-11, 13-17, 21-23, 25 and 27-29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

All the claims depend from either claim 1, 14, or 29 which contain the disputed language.

Claim 1 reads as follows:

> 1. A hydrogel wound dressing formed by spray delivery of a liquid composition to the wound, wherein the composition comprises water soluble PVA macromers having one or more pendant crosslinkable groups and the macromers crosslink to form a hydrogel *in situ* on the wound, wherein the pendant crosslinkable groups are acrylamide groups containing olefinically unsaturated groups, and wherein the composition includes a crosslinking initiator that is not bound to a macromer or another polymer. [bolding added]

Claim 14 reads as follows:

> 14. A method of forming a hydrogel would dressing, comprising the step of applying a composition to a wound via spray, wherein the composition comprises water soluble PVA macromers having one or more pendent crosslinkable groups and the macromers crossling to form a hydrogel on the wound, wherein the pendent crosslinkable groups are acrylamide groups containing olefinically unsaturated groups and wherein the composition includes a crosslinking initiator that is not bound to a macromer or another polymer. [bolding added].

> 29. A hydrogel wound dressing formed by spray delivery of a liquid composition to the wound, wherein the composition comprises water soluble PVA macromers having one or more pendent crosslinkable groups and the macromers crosslink to form a hydrogel *in situ* on the wound, wherein the pendent crosslinkable groups are acrylamide groups containing olefinically unsaturated groups, and wherein the

composition includes an unbound crosslinking initiator in solution. [bolding added]/

The Examiner found that the claim phrase "initiator that is not bound to a macromer or another polymer" introduces new matter that was not described in the specification as originally filed. (Final Rejection, Jun. 13, 2007, p. 2). Specifically, the Examiner found that the specification neither discloses an initiator that is "not bound," nor describes "another polymer" in the composition apart from the macromer. (Id.).

We note that, conceptually, the Appellants are trying to claim a "free" crosslinking initiator with this added language, by either the "not bound" or "unbound" language in the claims. The problem with written descriptive support for this concept arises because the specification does not use the term "free" or expressly describe the concept of an unbound initiator. The Appellants direct us to three examples in the specification in support of this term, which examples may or may not have unbound initiators.

The claim language "initiator that is not bound to a macromer or another polymer" appears to try to say the same thing as "free" - the initiator cannot be attached to macromers, or "another" polymer. The real question is - does this limitation find sufficient support in the specification?

We turn to the contested issues.

i) "another polymer"

The Appellants first challenge the Examiner's written description rejection by asserting that the claim phrase "another polymer" does not introduce new matter. (App. Br. 3). Specifically, the Appellants assert that "macromers are polymers" such that "the phrase 'another polymer' modifies

and refers to the macromer, not to a second polymer taught in the specification." (Id.).

The Appellants' position that these are not a "second" polymer is inconsistent with the claim language. The claim recites "macromer *or another polymer*." (Emphasis added). The "another polymer" is an express alternative to the macromer. We are unconvinced by the Appellant's narrow reading of the language as modifying "macromer" only. This first argument is therefore unpersuasive.

The Appellants next challenge the Examiner's written description rejection by asserting that "the specification [does not] need to have a specific statement that the initiators are unbound to satisfy this requirement." (App. Br. 4). The Appellants also assert that "[t]he term 'initiator' is used in the specification" in four instances to reference a photoinitiator, a redox initiator, and a borate initiator. (Id. p. 3)(citing Specification p. 9, ll. 22-25; p. 17, l. 13; p. 19, l. 1; p. 20, l. 2). According to the Appellants, in each instance that the term is used, "it is clear that the initiator is not bound to the macromer itself, or to another polymer." (App. Br. 3).

This argument gets to the heart of the matter. When we turn to the specification, we see that the above listed specific initiators are actually three specific examples, and that the specification does not clearly state that the intiators all must be unbound.

The Appellants' assert that the specification makes clear that these intiators are not bound to a macromer or another polymer. (App. Br. 3-4). However, there is insufficient evidence to support these statements in the

brief, and as such the assertions are merely attorney argument and not evidence.

20. For example, the Appellants state that Irgacure 2959 (Specification, p. 9, l. 23) is discussed in the specification and "it is clear that the initiator is not bound to the macromer itself, or to another polymer" (Br. at 3). The specification does not support this statement one way or the other. The same goes for the ferrous salt and borate. The specification does not describe that the photoinitiators, redox initiator, or borate initiator are initiators that are "not bound to a macromer or another polymer." (See Specification p. 9, ll. 22-25; p. 17, l. 13; p. 19, l. 1; p. 20, l. 2). While we do have the conclusory statements of counsel, we also have no evidence that these must be unbound. We also have no evidence that one of ordinary skill in the art would understand the examples as describing unbound initiators. Consequently, the appellant's position is without sufficient evidentiary support.

Accordingly, we affirm the Examiner's written description rejection.

II. The Obviousness Rejections.

a) Claims 1, 2, 8, 9 and 29 stand rejected under 35 U.S.C. § 103(a) over Chudzik.

Chudzik describes a hydrogel wound dressing that is applied to the wound site as a liquid composition and forms a flexible polymeric matrix upon exposure to light, i.e., hydrogel formed *in situ*." (Final Rejection, Jun. 13, 2007, p. 4). The Chudzik composition comprises a crosslinkable macromer and includes two or more polymer pendant polymerizable groups. (Id.).

Chudzik describes that the macromer includes a water-soluble, degradable polymer, such as polyvinyl alcohol (PVA), and acrylamide as the pendant polymerizable groups wherein the acrylamide groups contain olefinically unsaturated groups. (Id. pp. 4-5). Chudzik describes that the hydrogel may comprise therapeutic agents, including growth factor, antimicrobial agents and antithrombotics agents. (Id. p. 5). Chudzik discloses that initiators can be polymer-bound or non-polymer bound. (Id.). Chudzik teaches that polymer-bound initiator forms matrices more rapidly and completely than non-polymer bound initiator when exposed to light energy. (Id.).

The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a hydrogel composition comprising crosslinkable PVA macromer having one or more polymer pendant polymerizable group of acrylamide, as described by Chudzik, and to select the non-polymer bound initiator also disclosed by Chudzik, to delay matrices formation until the composition is sprayed on the site of the wound. (Id. pp. 5-6).

However, the Examiner found that Chudzik does not describe that the composition is delivered by spray or that the composition may contain an active agent that delivers NO (nitric oxide) to the wound. (Id. 8).

The Appellants assert that the Examiner erred in rejecting claims 1, 2, 8, 9 and 29, as obvious because Chudzik does not teach or suggest a wound dressing comprising an unbound initiator. (App. Br. 4). According to the Appellants, Chudzik describes "initiators that are bound to the backbone of either the polymer or macromer." (Id.). The Appellants further assert that to

the extent that Chudzik discloses unbound initiators, the reference teaches away from their use because they can present issues of toxicity, efficacy, and solubility. (Id.). Specifically, the Appellants assert that Chudzik teaches that the "non-polymer-bound initiator is not as good." (Id.)(emphasis omitted).

These arguments are not persuasive.

First, Chudzik describes preparing and evaluating two polymer solutions, one containing a polymer-bound initiator and one containing non-polymer-bound initiator. (Chudzik14:45-15:32). According to Chudzik, the polymer solution containing the bound initiator "formed matrices more rapidly and more completely" than the polymer solution containing the unbound initiator. (15:28-31).

In other words, with regard to matrix formation, Chudzik describes that a polymer solution containing unbound initiator is inferior to a solution with bound initiator. However, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley,* 27 F.3d at 553.

Second, Chudzik describes that a known process of preparing biodegradable and biostable hydrogels involving the polymerization of preformed macromers using low molecular weight initiators involves drawbacks such as "toxicity, efficacy, and solubility considerations." (Chudzik 2:10-16). To the extent that the Appellants assert that this disclosure relates to and teaches away from the use of unbound initiators, the argument remains unpersuasive.

Chudzik merely lists possible drawbacks. Chudzik characterizes these drawbacks in terms of "considerations" and further describes that "the initiator *may* involve some toxic consequence." (Id. 2:19-20)(emphasis added). A teaching of drawback considerations and potential consequences does not, standing alone, *per se* suggest that "the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant," so as to constitute a teaching away. *See In re Gurley,* 27 F.3d at 553.

The Appellants next assert that the Examiner's obviousness objection is erroneous because the cited prior art "does not teach a wound dressing formed by spray delivery of a liquid composition." (App. Br. 5). We take this argument to be made consistent with the constraints of 37 CFR § 1.56(b)(2)(i), in that the Appellants and their counsel must therefore be unaware of noncumulative art which would be material to patentability as regards this element of the claim .

We agree with the Appellants that Chudzik alone does not specifically describe a spray delivery, but does describe syringe application, catheter, and dipping.

However, the Appellants' argument fails to consider the combined references in view of the level of ordinary skill in the art at the time of the invention. As our reviewing Court has instructed, "[t]he question of obviousness cannot be approached on the basis that an artisan having ordinary skill would have known only what was read in the references, because such artisan must be presumed to know something about the art apart from what the references disclose." *See In re Jacoby*, 309 F.2d at 516.

The Appellants, in the specification, acknowledge that aerosol spray delivery systems for liquid compositions were known in the art at the time of the invention. The specification states, "Aerosol devices such as the Preval® aerosol spray unit available from Precision Valve Corporation, NY, USA, can be used." (Specification p. 11, ll. 17-18).

The Appellants are claiming a known delivery method for delivering a a hydrogel wound dressing to its usual location on the skin. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007). The Appellants have not shown that an aerosol delivery device is beyond the skill of one of ordinary skill in the art.

Consequently, we conclude that the Appellants have not established error with the Examiner's rejection.

b) Claims 3, 4, 10, 11, 13-17, 21-23, 25, 27 and 28 stand rejected under 35 U.S.C. § 103(a) over the combination of Chudzik and Sawhney.

Sawhney – Spray Delivery

Turning to the second reference, the Examiner found that Sawhney describes a composition and method of forming an *in situ* tissue adherent barrier comprising crosslinkable components using a spray delivery system. (Id. 9). The Examiner also found that the components are in the form of a solution and comprise water-soluble, crosslinkable, biodegradable macromers. (Id.).

The Examiner determined that it would have been obvious to a person of ordinary skill in the art at the time of the invention to provide the invention of Chudzik, using the non-polymer bound initiator also disclosed by Chudzik, and to deliver the composition with a spray delivery system, as described by Sawhney. (Id.).

Claims 3, 11, 13-16, 21-22, 25, 27 and 28

The Appellants next assert that claims 3, 11, 13-16, 21-22, 25, 27 and 28 are not obvious over the combined prior art because "[t]here exists no reason to combine the teachings of the references," and "even if the references are combined, the claimed invention does not result." (App. Br. 7).

Claim 3 recites, "The wound dressing of claim 1, wherein the composition is delivered via an aerosol delivery device." (App. Br. Appendix 9).

Specifically, the Appellants challenge Chudzik for the same reasons asserted, supra. Regarding Sawhney, the Appellants assert that the reference teaches a PEG macromer and not the claimed PVA macromer. (Id.).

This argument is not persuasive. The Appellants cannot overcome this obviousness rejection "by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). In this instance, the cited combination of references discloses all of the limitations of claims.

As discussed, supra, we found that Chudzik describes a composition comprising PVA macromers and an initiator that is not bound to a macromer or another polymer, as claimed. The Examiner relied upon Sawhney in the combination for teaching the formation of a wound dressing by spray delivery, as claimed. (*See* Final Rejection, Jun. 13, 2007, p. 8).

As the Examiner correctly determined, it would have been obvious to a person of ordinary skill in the art at the time of the invention to form Chadwick's hydrogel composition as a wound dressing using a spray delivery system because Sawhney teaches that spray delivery of crosslinking macromers forms an effective tissue adherent coating *in situ*. (See id. p. 9).

Consequently, we are not persuaded of error on the part of the Examiner.

Claims 4 and 17

Claim 4 recites, "The wound dressing of claim 1, wherein the composition is delivered via a pump spray delivery device." (App. Br. App. p. 9). Similarly, Claim 17 recites, "The method of claim 14, wherein the composition is delivered via a pump spray delivery device." (Id. p. 10).

The Appellants assert that neither Chudzik nor Sawhney teaches the use of a pump spray device. (App. Br. 7). The Appellants further assert that Sawhney relies upon a spray device using a gas discharge and that the

claim limitation of a "pump spray delivery device" renders the claims patentable.

This argument is also unpersuasive. As the Appellants acknowledge, Sawhney teaches the use of a spray device that relies upon gas discharge. (See App. Br. 7). Further, pump spray delivery devices were well known in the art long before the time of the invention, and the Appellants do not contend otherwise with persuasive evidence or reasoning. The simple substitution of Shawnee's spray device that relies upon gas flow with a spray device that relies upon a pump would have been obvious to one of ordinary skill in the art at the time the invention was made. As stated in *In re Fout*, 675 F.2d 297, 301 (CCPA 1982), "Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious."

Consequently, we do not find that the Appellants have established error on the part of the Examiner.

Claims 10 and 23

Claims 10 and 23 depend from claims 8 and 21. Claims 8 and 21 recite that "the composition further contains one or more additives selected from the group consisting of preservatives, biologically active agents, defoamers, wetting agents, leveling agents, hydrating agents, thickeners, fillers and absorbents." (App. Br. App. 9-10).

Claims 10 and 23 recite that the active agent, listed as one of the potential additives in the Markush group recited in claims 8 and 21, is "one which delivers NO [nitric oxide] to the wound." (Id. pp. 9, 11).

The Examiner found that Chudzik describes the application of antithrombogenics (col. 9, ll. 9) and as such, it would have been within the level of ordinary skill to select the appropriate agent.

The Appellants assert only that "[n]either patent teaches the delivery of nitric oxide (NO) to the wound using the wound dressing." (App. Br. 7). Insofar as the Appellants suggest that, therefore claims 10 and 23 must be patentable, we disagree. The Examiner found nitric oxide is an antithrombotic and that it would have been obvious to use nitric oxide in the Chudzik composition. (FF15). Appellants have put forth no persuasive evidence to the contrary, or that the selection of nitrous oxide would not have been obvious to the skilled artisan seeking wound dressings.

As a result, we find that the Appellants have not established that the Examiner erred in rejecting claims 10 and 23 as obvious over the prior art.

Accordingly, we affirm the Examiner's rejections.

CONCLUSIONS OF LAW

On the record before us, the Appellants have not shown error on the part of the Examiner. The claim phrase "initiator that is not bound to a macromer or another polymer" introduces new matter that is not adequately described in the original written description. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the known macromer and initiator for their known functions.

DECISION

The Rejection of claims 1-4, 8-11, 13-17, 21-23, 25 and 27-29 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is AFFIRMED.

The Rejection of claim 1, 2, 8, 9 and 29 under 35 U.S.C. § 103(a) over Chudzik (US Patent 6,007,833) is AFFIRMED.

The Rejection of claims 3, 4, 10, 11, 13-17, 21-23, 25, 27 and 28 under 35 U.S.C. § 103(a) over the combination of Chudzik and Sawhney (US 6,179,862 B1) is AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

ack

cc:

LAW OFFICE OF COLLEN A. BEARD, LLC
P. O. BOX 1064
DECATUR, GA 30031 - 1064